

K253437 Spiro-VISTAJun 12, 2026
254 days to decisionK253437 · Product code: **BTR** · Anesthesiology
Source: <https://www.510kdatabase.net/k253437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Oct 1, 2025
Decision date	Jun 12, 2026
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spiro Robotics
Location	Hayward, CA, US
Contact	Jackie Dulken
510(k) history	1 submissions · 1 cleared · 2026-2026

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